

K932866 RESOLUT REGENERATIVE MATERIALMar 28, 1995
652 days to decisionK932866 · Product code: **LYC** · Dental
Source: <https://www.510kdatabase.net/k932866/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bone Grafting Material, Synthetic (LYC)
Date received	Jun 14, 1993
Decision date	Mar 28, 1995
Days to decision	652 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	W.L. Gore & Associates, Inc.
Location	Mchenry, IL, US
Contact	MARY EDWARDS
Website	http://www.gore.com/
510(k) history	163 submissions · 148 cleared · 1980-2025

W.L. Gore & Associates, Inc. is a global materials science company specializing in advanced medical devices. The company operates with a manufacturing facility in McHenry, US. The company has received FDA 510(k) clearances from total submissions since its first clearance in 1980. Cardiovascular devices represent a dominant category, including vascular grafts and balloon catheters. Recent clearances also span general surgery, plastic surgery, and gastroenterology applications. The latest FDA 510(k) clearance in 2025 reflects ongoing regulatory activity. W.L. Gore & Associa...
